045-0139

MARYLAND DEPARTMENT OF THE ENVIRONMENT
1800 Washington Boulevard • Baltimore MD 21230
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Martin O'Malley
Governor

Anthony G. Brown
Lieutenant Governor

Shari T. Wilson
Secretary

Robert M. Summers, Ph.D.
Deputy Secretary

NOV 17 2009

Mr. Michael Viner
Trinity Sterile Inc.
201 Kiley Drive
Salisbury, Maryland 21804

Dear Mr. Viner:

Enclosed please find your premises wide Permit to Construct for the Trinity Sterile Inc. facility located at 201 Kiley Drive in Salisbury, Maryland. The permit contains both general conditions, which apply to all air quality permit holders in Maryland, and specific conditions, which apply to the ethylene oxide sterilizer that you have proposed to modify.

The permit to construct includes operational limitations in order that Trinity Sterile Inc. will not emit ethylene oxide at levels not permissible under Maryland's Air Toxics regulations. Trinity Sterile Inc. will remain in compliance with Maryland's Air Toxics regulations so long as Trinity Sterile Inc. complies with the permit conditions or until such time that the limits are not required.

A performance test of both the sterilization chamber control and the aeration room control will be required to determine that the required 99% control efficiency can be attained when each respective vent (SCV and ARV) is being vented to the scrubber. Once the performance test is completed and Trinity Sterile Inc. demonstrates compliance with the requirements of the permit to construct, Trinity is required to submit a State Permit to Operate amendment application with the performance testing results. The amended state PTO will supersede the current State PTO issued on March 1, 2009 and will expire on February 28, 2014.

If you have any questions regarding the issuance of this permit, please contact Christopher Beck at (410) 537-4415.

Sincerely,

Karen G. Irons, P.E., Administrator
Air Quality Permits Program
Air and Radiation Management Administration

KGI/aw

Enclosure

cc: Wicomico County Health Department

C

KEEP PERMIT AT SITE **CONTROL NO. B- 02467**

State of Maryland

Martin O' Malley
Governor

Shari T. Wilson
Secretary

DEPARTMENT OF THE ENVIRONMENT

Air and Radiation Management Administration
1800 Washington Boulevard, Suite 720
Baltimore, MD 21230

[X] Construction Permit [ ] Operating Permit

PERMIT NO. (as listed on Page 2) DATE ISSUED November 17, 2009

PERMIT FEE N/A EXPIRATION DATE In accordance with COMAR 26.11.02.04B

LEGAL OWNER & ADDRESS

Trinity Sterile, Inc.
201 Kiley Drive
Salisbury MD 21801
Attn: Mr. Michael Viner

SITE

Trinity Sterile, Inc.
201 Kiley Drive
Salisbury MD 21801
WICOMICO County
Premises# - 045-0139 AI# - 1506

SOURCE DESCRIPTION

An ethylene oxide sterilization facility.

This permit authorizes an increase in the 12-month rolling ethylene oxide usage for a ethylene oxide sterilization chamber and two (2) aeration rooms controlled by a Deoxx wet acid scrubber system (ARMA Registration No. 045-0139-7-0023) for the sterilization of medical devices.

This permit supersedes all previous permits to construct issued to Premises No. 045-0139.

This source is subject to the conditions described on the attached pages.

Program Manager

Director, Air and Radiation Management Administration

'PER.009 (Rev. 10-08-03) (NOT TRANSFERABLE)

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This permit-to-construct incorporates requirements for the following registered installation:

ARMA Registration No.	Description	Date of Installation
045-0139-7-0023	One ethylene oxide sterilization chamber and two (2) aeration rooms controlled by one (1) wet acid scrubber	1991 Modified in 2009

Part A – General Provisions

(1) The following Air and Radiation Management Administration (ARMA) permit-to-construct applications are incorporated into this permit by reference:

(a) Application for Processing or Manufacturing Equipment (Form 5) received August 28, 2009.

(b) Summary of Demonstrations for Meeting the Ambient Impact Requirement and T-BACT Requirements (Form 5A) received August 28, 2009.

(c) Emissions Data (Form 5B) received August 28, 2009.

(d) Application for Gas Cleaning or Emission Control Equipment (Form 6) received August 28, 2009.

If there are any conflicts between representations in this permit and representations in the applications, the representations in the permit shall govern. Estimates of dimensions, volumes, emissions rates, operating rates, feed rates and hours of operation included in the applications do not constitute enforceable numeric limits beyond the extent necessary for compliance with applicable requirements.

(2) Upon presentation of credentials, representatives of the Maryland Department of the Environment ("MDE" or the "Department") and the Wicomico County Health Department shall at any reasonable time be granted, without delay and without prior notification, access to the Permittee's property and permitted to:

(a) Inspect any construction authorized by this permit;

(b) Sample, as necessary to determine compliance with requirements of this permit, any materials stored or processed on-site, any waste materials, and any discharge into the environment;

(c) Inspect any monitoring equipment required by this permit;

(d) Review and copy any records, including all documents required to be maintained by this permit, relevant to a determination of compliance with requirements of this permit; and

(e) Obtain any photographic documentation or evidence necessary to determine compliance with the requirements of this permit.

(3) The Permittee shall notify the Department prior to increasing quantities and/or changing the types of any materials referenced in the application or limited by this permit. If the Department determines that such increases or changes constitute a modification, the Permittee shall obtain a permit-to-construct prior to implementing the modification.

(4) Nothing in this permit authorizes the violation of any rule or regulation or the creation of a nuisance or air pollution.

(5) If any provision of this permit is declared by proper authority to be invalid, the remaining provisions of the permit shall remain in effect.

(6) This permit supersedes all previous permits-to-construct issued under permit number 045-0139.

(7) Subsequent to issuance of this permit, the Department may impose additional and modified requirements that are incorporated into a State Permit-to-Operate issued pursuant to COMAR 26.11.02.13.

Part B – Applicable Regulations

(1) This source is subject to all applicable federal air pollution control requirements including, but not limited to, the following:

All applicable terms, provisions, emissions standards, testing, monitoring, record keeping, and reporting requirements included in the National Emissions Standards for Hazardous Air Pollutants (NESHAP) promulgated under 40 CFR 63, Subparts A and O for Ethylene Oxide Commercial Sterilization and Fumigation Operations.

All reports and notifications required under 40 CFR 63, Subparts A and O shall be submitted to the Compliance Program of the Department's Air and Radiation Management Administration.

(2) This source is subject to all applicable federally enforceable State air pollution control requirements including, but not limited to, the following regulations:

(a) COMAR 26.11.01.07C, which requires that the Permittee report to the Department occurrences of excess emissions.

(b) COMAR 26.11.02.09A, which requires that the Permittee obtain a permit-to-construct if an installation is to be modified in a manner that would cause changes in the quantity, nature, or characteristics of emissions from the installation as referenced in this permit.

(c) COMAR 26.11.06.02C(1), which limits visible emissions other than uncombined water to not more than 20 percent opacity.

(3) This source is subject to all applicable State-only enforceable air pollution control requirements including, but not limited to, the following regulations:

(a) COMAR 26.11.02.13A(65), which requires that the Permittee obtain from the Department, and maintain and renew as required, a valid State permit-to-operate.

(b) COMAR 26.11.02.19C & D, which require that the Permittee submit to the Department annual certifications of emissions, and that the Permittee maintain sufficient records to support the emissions information presented in such submittals.

(c) COMAR 26.11.06.08 and 26.11.06.09, which generally prohibit the discharge of emissions beyond the property line in such a manner that a nuisance or air pollution is created.

(d) COMAR 26.11.15.05, which requires that the Permittee implement "Best Available Control Technology for Toxics" (T – BACT) to control emissions of toxic air pollutants.

(e) COMAR 26.11.15.06, which prohibits the discharge of toxic air pollutants to the extent that such emissions would unreasonably endanger human health.

Part C – Construction Conditions

(1) Except as otherwise provided in this part, the manifolding of the two (2) aeration room vents to the existing wet acid scrubber shall be constructed in accordance with specifications included in the incorporated applications.

(2) The Permittee shall manifold the two (2) existing aeration room vents to the existing wet acid scrubber such that the exhaust gases from the two (2) aeration rooms vent through the wet acid scrubber prior to discharging to the atmosphere.

(3) The Permittee shall install an automated damper/valve to prevent the venting of gases from the sterilization chamber and the aeration rooms to the existing wet acid scrubber from occurring simultaneously.

Part D – Operating Conditions

(1) Except as otherwise provided in this part, the ethylene oxide sterilization chamber and the two (2) aeration rooms controlled by the wet acid scrubber shall be operated in accordance with specifications included in the application and any operating procedures recommended by equipment vendors unless the Permittee obtains from the Department written authorization for alternative operating procedures.

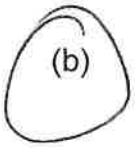
(2) Total ethylene oxide usage for the sterilization chamber shall not exceed 87 pounds per batch, unless the Permittee can demonstrate to the satisfaction of the Department, that compliance with the requirements of 40 CFR, § 63, Subpart O, and COMAR 26.11.15.06 can be achieved at a higher ethylene oxide usage rate.

(3) The exhaust gases from the sterilization chamber and the two (2) aeration rooms shall vent through the wet acid scrubber prior to discharging to the atmosphere.

(4) The Permittee shall operate the automated damper/valve in the manifold system to prevent the gases from the sterilization chamber and the aeration rooms from simultaneously venting to the wet acid scrubber.

(5) In order to maintain scrubber performance, the Permittee shall comply with one of the following operating limitations:

(a) The ethylene glycol concentration of the scrubber liquor in the scrubbing liquor tank shall not exceed the tank's maximum concentration as determined during the most recent stack emissions test approved by the Department; or



The level of the scrubber liquor in the scrubbing liquor tank shall not exceed the maximum level determined for the tank during the most recent stack emissions test approved by the Department. The maximum level correlates with the maximum concentration of ethylene glycol allowable in the scrubber liquor in order to comply with COMAR 26.11.15.06 and 40 CFR, § 63, Subpart O. Therefore, any improper draining of saturated scrubber liquor (scrubber liquor that contains the maximum concentration of ethylene glycol) to remain below the maximum level is prohibited.

(6) The wet acid scrubber shall be operated to achieve at least a 99.0% ethylene oxide emissions reduction from the ethylene oxide sterilization chamber in order to demonstrate compliance with the Maryland air toxics requirements of COMAR 26.11.15.06 and the sterilization control vent (SCV) emission limitations of 40 CFR, §63.362(c).

(7) The wet acid scrubber shall be operated to achieve at least a 99.0% ethylene oxide emissions reduction or reduce the outlet concentration to a maximum of one (1) ppmv from the aeration rooms in order to demonstrate compliance with the Maryland air toxics requirements of COMAR 26.11.15.06 and the aeration room vent (ARV) emission limitations of 40 CFR, §63.362(d).

Part E – Notification and Testing Requirements

(1) In accordance with 40 CFR §63.363(a)(1) and (2), within 180 days after initiating operation of the first aeration room exhaust cycle that vents to the wet acid scrubber, the Permittee shall conduct performance tests to determine compliance with 40 CFR §63.362 for the SCV and SRV. The performance test shall be conducted using the procedures listed in 40 CFR §63.7 according to the applicability in Table 1 of 40 CFR §63.360, the procedures listed in 40 CFR §63.363, and the test methods of 40 CFR §63.365.

(2) The Permittee shall notify the Department, in writing, of the date when the first aeration room exhaust cycle that vents to the wet acid scrubber is initiated within 15 days after such date.

(3) At least 30 days prior to the performance tests, the Permittee shall submit to the Department for review and approval, a test protocol that summarizes the test methods that will be employed and the operating parameters that will be monitored during the testing periods. Compliance with this requirement satisfies the requirement specified in 40 CFR, §63.9(e).

(4) In accordance with 40 CFR, §63.363(b)(1), the Permittee shall comply with the requirements of 40 CFR, §63.365(b) during the performance tests.

(5) In accordance with 40 CFR, §63.363(b)(2), the Permittee shall establish as a site-specific operating parameter during the performance test for the SCV in 40 CFR 63.365(b)(1) either:

(a) In accordance with 40 CFR, §63.363(b)(2)(i), the maximum ethylene glycol concentration using the procedures described in 40 CFR 63.365(e)(1); or

(b) In accordance with 40 CFR, §63.363(b)(2)(ii), the maximum liquor tank level using the procedures described in 40 CFR 63.365(e)(2).

(6) During the performance test for the SCV, in accordance with 40 CFR, §63.365(e)(1), the Permittee shall establish the maximum ethylene glycol concentration as the ethylene glycol concentration averaged over three (3) test runs. The sampling and analysis procedures in ASTM D 3695-88, Standard Test Method for Volatile Alcohols in Water by Direct Aqueous-Injection Gas Chromatography shall be used to determine the ethylene glycol concentration.

(7) In accordance with 40 CFR, §63.365(e)(2), the Permittee shall establish the maximum liquor tank level based on a single measurement of the liquor tank level during one test run during the performance test for the SCV.

(8) In accordance with 40 CFR, §63.7(g), the Permittee shall report the results of the performance tests to the Department within 60 days following the completion of the performance tests. The results of the performance tests shall be submitted as part of the notification of compliance status required under 40 CFR, §63.9(h).

(9) In accordance with 40 CFR, §63.9(h)(1) and (2) the Permittee shall submit to the Department a notification of compliance status, signed by a responsible official who shall certify its accuracy, attesting to whether the ethylene oxide sterilization chamber and aeration rooms controlled by the wet acid scrubber have complied with the relevant standards. The notification must be submitted no later than 60 days following the completion of the performance tests.

The notification shall include the following (if applicable):

(a) The methods that were used to determine compliance.

(b) The results of any performance test, opacity or visible emission observations, continuous monitoring system (CMS) performance evaluations, and/or other monitoring procedures or methods that were conducted.

(c) The methods that will be used for determining continuing compliance, including a description of monitoring and reporting requirements and test methods.

(d) The type and quantity of hazardous air pollutants emitted by the source (or surrogate pollutants if specified in the relevant standard), reported in units and averaging times and in accordance with the test methods specified in the relevant standard.

(e) If the relevant standard applies to both major and area sources, an analysis demonstrating whether the affected source is a major source (using the emissions data generated for this notification).

(f) A description of the air pollution control equipment (or method) for each emission point, including each control device (or method) for each hazardous air pollutant and the control efficiency (percent) for each control device (or method).

(g) A statement by the Permittee as to whether the source has complied with the relevant standard or other requirements.

Part F – Monitoring, Record Keeping and Reporting

(1) The Permittee shall submit a State Permit to Operate amendment application with the performance testing results demonstrating compliance.

(2) In accordance with 40 CFR, §63.364(b)(1) and (2), for the wet acid scrubber the Permittee shall either:

(a) Sample the scrubber liquor from the scrubbing liquor tank and analyze and record at least once per week, the ethylene glycol concentration of the scrubber liquor using the test methods and procedures in 40 CFR, §63.365(e)(1); or

(b) Measure and record once per week the level of the scrubber liquor in the scrubbing liquor recirculation tank. The Permittee shall install, maintain and use a liquid level indicator to measure the scrubber liquor tank level as indicated by a permanent mark on the tank determined during the most recent performance test approved by the Department. The maximum level correlates with the maximum concentration of ethylene glycol allowable in the scrubber liquor in order to comply with COMAR 26.11.15.06 and 40 CFR, § 63, Subpart O.

(3) The Permittee shall measure and record the specific gravity and the concentration of ethylene glycol in the "spent" scrubber liquor each time the scrubber liquor for the wet acid scrubber is replaced.

(4) The Permittee shall comply with the record keeping requirements in 40 CFR Part 63.10(b) of Subpart A for the ethylene oxide sterilization chamber and the aeration rooms according to the applicability in Table 1 of 40 CFR Part 63.360. The requirements of 40 CFR Part 63.10(b) of Subpart A require the Permittee to maintain on site records including, but not limited to, the following:

(a) The occurrence and duration of each malfunction of the required air pollution control and monitoring equipment.

(b) All required measurements needed to demonstrate compliance with a relevant standard (including, but not limited to, raw performance testing measurements and raw performance evaluation measurements).

(c) All results of performance tests and all measurements that may be necessary to determine the condition of performance tests and performance evaluations.

(d) All documentation supporting the notification of compliance status under 40 CFR Part 63.9.

(5) The Permittee shall maintain for at least five (5) years, and shall make available to the Department upon request, records of the following information:

(a) Records of weekly logs of the specific gravity and ethylene glycol concentration in the scrubber solution or the weekly tank level analysis for the scrubber liquor tank including the date of the analysis and the results.

(b) Records of the date, specific gravity, and ethylene glycol concentration in the scrubber solution when the scrubber liquor solution is replaced.

(c) Records of the amount of ethylene oxide used per batch for each sterilization cycle.

(6) The Permittee shall submit to the Department and Region III of the U.S. Environmental Protection Agency (EPA), an ongoing compliance status report for each six (6) month period beginning January 1 and July 1 of each year as required by 40 CFR Part 63.10 (a), (d), (e), and (f) and Part 63.366(a) and (c). The Permittee shall submit the reports within 30 days after the end of each six (6) month period.

(7) The Permittee shall comply with the requirements of 40 CFR Part 63.366(a)(3) for the content and submittal dates for excess emissions and monitoring system performance reports.

(8) The Permittee shall maintain at the facility for at least five (5) years, and shall make available to the Department upon request, records necessary to support annual certifications of emissions and demonstrations of compliance for toxic air pollutants. Such records shall include, if applicable, the following:

(a) Mass emissions rates for each regulated pollutant, and the total mass emissions rate for all regulated pollutants for each registered source of emissions;

(b) Accounts of the methods and assumptions used to quantify emissions;

(c) All operating data, including operating schedules and production data, that were used in determinations of emissions;

(d) Any records, the maintenance of which is required by this permit or by State or federal regulations, that pertain to the operation and maintenance of continuous emissions monitors, including:

(i) All emissions data generated by such monitors;

(ii) All monitor calibration data;

(iii) Information regarding the percentage of time each monitor was available for service; and

(iv) Information concerning any equipment malfunctions.

(e) Information concerning operation, maintenance, and performance of air pollution control equipment and compliance monitoring equipment, including:

(i) Identifications and descriptions of all such equipment;

(ii) Operating schedules for each item of such equipment;

(iii) Accounts of any significant maintenance performed;

(iv) Accounts of all malfunctions and outages; and

(v) Accounts of any episodes of reduced efficiency.

(f) Limitations on source operation or any work practice standards that significantly affect emissions; and

(g) Other relevant information as required by the Department.

(9) The Permittee shall submit to the Department by April 1 of each year a certification of emissions for the previous calendar year. The certifications shall be prepared in accordance with requirements, as applicable, adopted under COMAR 26.11.01.05 – 1 and COMAR 26.11.02.19D.

(a) Certifications of emissions shall be submitted on forms obtained from the Department.

(b) A certification of emissions shall include mass emissions rates for each regulated pollutant, and the total mass emissions rate for all regulated pollutants for each of the facility's registered sources of emissions.

(c) The person responsible for a certification of emissions shall certify the submittal to the Department in the following manner:

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

(10) The Permittee shall submit to the Department by April 1 of each year a written certification of the results of an analysis of emissions of toxic air pollutants from the Permittee's facility during the previous calendar year. Such analysis shall include either:

(a) A statement that previously submitted compliance demonstrations for emissions of toxic air pollutants remain valid; or

(b) A revised compliance demonstration, developed in accordance with requirements included under COMAR 26.11.15 & 16, that accounts for changes in operations, analytical methods, emissions determinations, or other factors that have invalidated previous demonstrations.

(11) The Permittee shall report, in accordance with requirements under COMAR 26.11.01.07, occurrences of excess emissions to the Compliance Program of the Air and Radiation Management Administration.